EPA's Ecological Risk Assessment Initiative:

Progress Report of the Ecological Committee on FIFRA Risk Assessment Methods: 1. Workgroup Formation and Process.

I. M. Sunzenauer, and D.S. Spatz,
Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC 20460; and
D. Fischer, Agriculture Division, Bayer Corporation, Stilwell, KS 66085

May 1996

The Environmental Fate and Effects Division within the Office of Pesticide Programs presented their Ecological Risk Assessment Methodology to the FIFRA Scientific Advisory Panel (SAP).

SAP Recommendations

While recognizing and generally reaffirming the utility of OPP's current ecological risk assessments, the Panel indicated that OPP, due to data gaps, is "trapped" in single point deterministic risk assessments and should move toward probabilistic types of assessments that address the magnitude, uncertainty and variation involved in the provided estimates.

EFED Response to the SAP

- Commitment to design a process for developing and validating probabilistic assessment tools and methodologies.
- Methods developed will reflect a solid foundation in environmental toxicology and environmental fate, including the transport, degradation, and accumulation of pesticides in the environment.
- Commitment to involve stakeholders- outreach.

December 1996

Formation of the Workshop Organizing Committee (WOK)

Edward Fite, EPA
Paul Mastradone, EPA
Ron Parker, EPA
Dana Spatz, EPA
Ann Stavola, EPA
Ingrid Sunzenauer, EPA
Jim Wolf, EPA

Dave Fischer, Bayer Corp.
Jim Gagne, Am. Cyanamid
Dennis Laskowski, Dow Elanco
Ray McAllister, ACPA
Kevin Reinert, Rohm and Haas
Rick Stanton, Valent USA

Responsibilities and Accomplishments of the WOK

- Outreach-
  Pesticide Program Dialog Committee (PPDC)
  State FIFRA Issues Research and Evaluation Group (SFIREG)
  Professional Meetings (ACS, SETAC, SRA)

- Invited participants to ECOFRAM- aquatic and terrestrial workgroups.

- Held June 23, 1997 open workshop. "Evaluating Ecological Risk: Developing FIFRA Probabilistic Tools and Processes."

- Two additional workshops are planned. Summer 1998- workgroups will share results and obtain peer review. Fall 1998- open meeting for ECOFRAM to share final results and recommendations.

June 1997

Formation of the Ecological Committee On FIFRA Risk Assessment Methods (ECOFRAM)

- Responsible for conducting the primary review of the current assessment process and developing new tools and methodologies.

- Identify additional methods, development and validation needs to ensure that the assessment process supports environmental decisions that are scientifically defensible.

1001 Risk Manager Questions

- What is the magnitude and probability of these effects?
- What are the effects of concern?
- Why are they of concern?
- Will there be population(s) impacts?
- Will the population(s) recover?
- Are the effects seen across different species?
- Will the effects influence density and diversity?
- How confident are we in our estimate of the effects?
- What models did we use? Have they been validated? Are they widely accepted and scientifically sound?
- Is there any monitoring data? Which data are more reliable, lab or monitoring? How have you factored the monitoring data into your assessment?

Charge to the Terrestrial and Aquatic Workgroups

- Develop processes and tools for predicting the magnitude and probabilities of adverse effects to non-target aquatic and terrestrial species resulting from the use of pesticides.

- Standardized procedures that integrate estimates of pesticide exposure with knowledge about potential adverse effects. Account for biological factors such as species sensitivity, habitat, dietary/behavior mechanisms. Account for environmental factors such as transport, accumulation, fate, climate, application techniques, and formulation.

- Address uncertainty in a quantitative manner and recommend procedures to appropriately validate tools and assumptions.

- Keep within the context of the FIFRA regulatory perspective and follow the outline provided by EPA's Framework for Ecological Risk Assessment (U.S. EPA/ORD, 1992).

Workgroup Members: Aquatic

Exposure

Paul Hendley (Chair)- Zeneca
James Baker- Iowa State Univ.
Lawrence Burns- ORD/EPA
David Farrar- OPP/EPA
Alan Hosmer- Novartis
R. David Jones- OPP/EPA
Walton Low- USGS
Mark Russell- Du Pont
Mari Stavanja- FL Bureau of Pesticide
W. Martin Williams- Waterborne Env.
James Wolf- OPP/EPA

Effects

Jeff Giddings (Chair)- Springborn
Larry Barnthouse- McLaren-Hart
Jerry Clark- Natl. Fish & Wildlife Fou.
A. Tilghman Hall- Bayer
Michael McKee- Monsanto
Michael Newman- Univ. of Georgia
Kevin Reinert- Rohm and Haas
Robert Sebastien- Health Canada
Ann Stavola- OPP/EPA
Keith Solomon- Univ. of Guelph
Les Touart- OPP/EPA
Randy Wentsel- U.S. Army

Workgroup Members: Terrestrial

Exposure

Edward Fite (Chair)- OPP/EPA
Larry Brewer- Ecotox. & Biosystems
Kristin Brugger- Du Pont
David Fischer- Bayer
Andy Hart- UK MAFF
Dennis Laskowski- DowElanco
Paul Mastradone- OPP/EPA
Robert Menzer- ORD/EPA
Daryl Morehead- Texas Tech Univ.
Henry Nelson- OPP/EPA
Raymond O'Connor- Univ. of Maine
Ron Parker- OPP/EPA
Duane Wolf- Univ. of Arkansas

Effects

Michael Willig (Chair)- Texas Tech
Alain Baril- Environment Canada
Richard Bennett- Eco. Planning & Tox
John Eisemann- OPP/EPA
William Erickson- OPP/EPA
Susan Ferenc- USDA
Michael Fry- National Audubon Soc.
James Gagne- American Cyanamid
Michael Hooper- Clemson Univ.
Thomas Lacher- Texas A&M
Monte Mayes- Dow Chemical
Diana Post- Rachel Carson Council
Robert Ringer- Michigan State (Ret.)
Jennifer Shaw- Zeneca

August 1997

Progress of ECOFRAM Workgroups

Terrestrial Workgroup Approach

- Define assessment questions (probability and magnitude of effects).
- Develop conceptual model (exposure and effects).
- Identify major variables that influence effects to nontarget species.
- Define distribution for these variables or how to estimate them.
- Construct models and perform sensitivity analysis.
- Identify data needed to support models.
- Develop risk assessment process incorporating the models.
- Define additional developmental work and validation requirements.

Aquatic Workgroup Approach

- Time-to-event analysis
- Pulsed exposures
- Life table and population models
- Intraspecific variability in sensitivity
- Interspecific variability in sensitivity
- Sensitivity distribution subsets, resampling
- Ecosystem models
- Mesocosms
- Behavioral effects
- Sediment toxicity/Equilibrium partitioning

Milestones

✓ Formation of WOK	December 1996
✓ Formation of ECOFRAM and Initial Outreach Workshop	June 1997
✓ Consultation with SAP	September 1997
✓ Presentation of Interim Progress at Professional Society Meetings	Fall/Winter 1997
► ECOFRAM Reports	Spring 1998
► Peer Review Workshop	Fall 1998
► SAP Review of Proposed Ecological Risk Assessment Improvements	Winter 1998
► OPP Implements Use of New Tools and Processes	Spring 1999

www.epa.gov/oppefed1/ecorisk/index.htm